

**REMARKS**

Claims 1 to 8 and 17 are pending. Reconsideration of the application is requested.

**§ 112 Rejections**

Claims 3 and 4 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse.

Claims 3 and 4, each being dependent upon claim 1, incorporate all of the features thereof. Claim 1 sets a lower and upper value to the range of surface area values. Claims 3 and 4 each more narrowly specify an upper value to the range. The lower value of the range as recited in claim 1 is left unchanged.

There is no uncertainty that by specifying an upper value to the range, claims 3 and 4 further limit claim 1 without the need for separately specifying that they do not change the lower range value feature, which is incorporated due to dependent claims 3 and 4 reference to claim 1. This is no different than any other dependent claim which incorporates all of the features of the independent claim to which it refers without the need to separately recite those features again in the dependent claim.

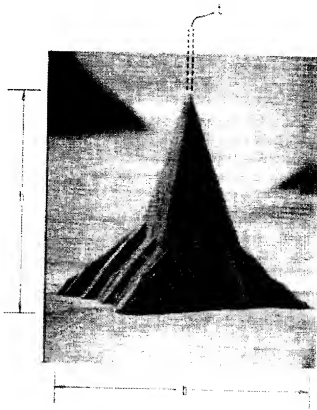
In summary, Applicants submits that the rejection of claims 3 and 4 under 35 USC § 112, second paragraph is inappropriate and that the rejection should be withdrawn.

**§ 102 Rejections**

Claims 1-8 and 17 are rejected under 35 USC § 102(b) as being anticipated by Trimmer (WO 96/10630). Applicants respectfully traverse.

*Claim 1*

Trimmer provides, at the cited passage of page 7, line 20 to page 8, line 11, a description of Figure 1B therein. Figure 1B of Trimmer is reproduced below.

**FIG. 1B**

Applicants acknowledge that in one portion of Trimmer, reference is made to the microprobes having four-sided truncated pyramid shapes. See page 7, lines 13 to 19 (not cited by the Patent Office) This discussion is not made, however, in the context of Figure 1B. Thus, any feature dimensions discussed in the context of 1B are not tied to the disclosure of truncated pyramids.

Furthermore, in this discussion of truncated pyramids, Trimmer does not specify that such structures have “flat tips” (as recited in claim 1) as asserted by the Patent Office.

Separately, in the context of Figure 1B, Trimmer does recite that “The tip width  $t$  of the microprobes will usually vary from about 0.05 to about 10 microns, and is preferably no more than about 1 micron.” See Trimmer, page 7, lines 34 to 37.

It is not clear, however, from Figure 1B that Trimmer is at all describing a truncated pyramid having such dimensions. Indeed, it is impossible to ascertain from the Figure 1B of

Trimmer whether the pyramid is so-truncated. It may well be that Figure 1B of Trimmer represents a sharp tipped needle with an edge having a width of  $t$  rather than a truncated pyramid.

Thus, there is no direct teaching of Trimmer that ties the values of  $t$  to an embodiment that is a truncated pyramid. Accordingly, the Patent Office assertion that such teaching is present in Trimmer is in error and the rejection is inappropriate and should be withdrawn.

Even if the Patent Office were to maintain that the combination of features taught in Trimmer were rendered obvious even though not explicitly taught by Trimmer, Applicants respectfully disagree. Trimmer teaches values of  $t$  ranging from 0.05 microns to about 10 microns. Thus, the resulting surface area range, if such values were associated with square pyramidal planar surfaces, would range from 0.0025 microns to 100 microns, a range of 40,000:1.

Such a large range highlights the importance of more specific teachings of Trimmer to select specific values within the range. To the extent Trimmer provides any such guidance, it teaches that the value of  $t$  is “preferably no more than about 1 micron.” See page 7, lines 36 and 37. This would, of course, provide a microprobe capable of piercing an individual cell, as contemplated by Trimmer, but would give a surface area of 1 micron, well outside the range of claim 1.

Therefore, even if these separate features of Trimmer which are never combined by Trimmer itself are combined by the Patent Office in a rejection of claim 1 as obvious over the teachings of Trimmer, such a rejection would be misplaced as the present claims represent a selection of values that are well outside the specific selection criteria taught by Trimmer.

For at least these reasons, the Patent Office rejection of claim 1 over Trimmer is inappropriate and Applicants kindly request that it be withdrawn.

#### *Claim 8*

Claim 8 provides, in part, a plurality of microneedles “wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape; wherein the flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less.”

Thus, for at least the reasons discussed above with regard to claim 1, the Patent Office has failed to show where Trimmer teaches, suggests or describes each and every feature of claim 8 and

the rejection of claim 8 under 35 USC §102(b) over Trimmer is inappropriate and should be withdrawn.

*Claim 17*

Claim 17 recites a method of using a microneedle device, the method comprising: providing a microneedle device according to claim 1; contacting the skin on a patient with the at least one microneedle; forcing the microneedle device against the skin.

The rejection of claim 17, which is dependent on claim 1, over Trimmer is inappropriate for at least the reasons discussed above with regard to claim 1.

The Patent Office makes a conclusory statement that the needles of Trimmer are being used to contact the skin, but does not provide any citation or support for such assertion. Accordingly, the rejection fails to meet the minimum requirements as set forth in MPEP 2131 of identifying where the cited reference teaches, suggests or describes each and every feature of the claimed invention. Therefore, Applicants respectfully submit that the rejection is inappropriate and request that it too be withdrawn.

Claims 2 to 7 each depend from claim 1 and add patentable features thereto. For at least the reasons discussed above with regard to claim 1, the rejection of these claims should be withdrawn as well.

The rejection of claims 1–8 and 17 under 35 USC § 102(b) as being anticipated by Trimmer is inappropriate and should be withdrawn.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application is requested.

Respectfully submitted,

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Date

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